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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/746,567	12/21/2000	Angel Cebolla Ramirez	AM-00106.P.1-US	1592

24232 7590 07/25/2003

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SAN DIEGO, CA 92130

EXAMINER
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SULLIVAN, DANIEL M

ART UNIT	PAPER NUMBER
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1636

16

DATE MAILED: 07/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/746,567

Applicant(s)

CEBOLLA RAMIREZ ET AL.

Examiner

Daniel M Sullivan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 82-115 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 82-95 and 98-115 is/are allowed.
- 6) ☒ Claim(s) 96 is/are rejected.
- 7) ☒ Claim(s) 97 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 May 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other:  |

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### **DETAILED ACTION**

This Office Action is a response to the "Response to Office Action" filed 14 May 2003 (Paper No. 14) in reply to the Non-Final Office Action mailed 29 January 2003 (Paper No. 12). Claims 42 and 47 were withdrawn from consideration and claims 48-81 were considered in Paper No. 12. Claims 42, 47 and 48-81 were canceled and claims 82-115 were added in Paper No. 14. Claims 82-115 are pending and under consideration.

#### ***Response to Amendment***

Rejection of claim 48-81 is rendered moot by cancellation of the claims.

Claims 82-115 are free of the art of record. The art does not teach or suggest the particulars to which the cascade genetic circuit of the instant claims are limited. Specifically, Aubrecht *et al.* (1996) *Gene* 172:227-231, previously cited against claims 48, 52-54, 60, 62-64, 67, 68, 70-73, 76-78 and 81 does not contemplate a cascade genetic circuit comprising Nah-R and XylS2 transcriptional regulators, and Psa1 and Pm promoters. Although these regulatory elements were known in the art at the time of filing, the art does not suggest construction of a cascade genetic circuit comprising said elements.

#### ***New Grounds Necessitated by Amendment***

##### **Claim Objections**

Claims 82, 93 and 110 are objected to because of the following informalities: The claims contain typographical errors. Specifically, in line 11 of claims 82 and 93, the word "or" should

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be “of” and in the first line of claim 110, the word “for” is missing between the words “method and “inducing”. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 96 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

*Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111, clearly states that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the ‘written description’ inquiry, *whatever is now claimed*.” (See page 1117.) The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See *Vas-Cath* at page 1116).

In the instant case, the claims are directed to a cascade genetic circuit wherein the Nah-R transcriptional regulator, which is responsive to one or more benzoate derivatives and activates the Psa1 promoter, is a mutant form of Nah-R. The metes and bounds of the term “mutant form” are not specifically set forth in the specification. Therefore, the mutant form of Nah-R is

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understood to broadly encompass any and all modifications of Nah-R having the recited function.

The Guidelines for Written Description state “when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus”, “In an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus” (Federal Register, Vol. 66, No. 4, Column 2, page 71436). In the instant case, the specification sets forth the nahR3 and nahR4 mutants of Nah-R as representative species of the genus encompassed by Nah-R mutants. However, two species are clearly not representative of the full genus of all mutants of NahR4 that are responsive to one or more benzoate derivatives and activates the Psa1 promoter.

Beyond these two examples, the description of Nah-R mutants is limited only by function, with no disclosure of the structural requirements which determine said function. An adequate written description of a transcriptional regulator requires more than a mere statement that it is part of the invention and a recitation of its function; what is required is a description of the transcriptional regulator itself. It is not sufficient to define protein solely by its principal biological property (i.e., it is responsive to one or more benzoate derivatives and activates the Psa1 promoter) because disclosure of no more than that, as in the instant case, is simply a wish to know the identity of any transcriptional regulator with that biological property. Also, naming a type of material generically known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. Thus, claiming all mutants of Nah-R that achieve a result without defining what means will do is not in compliance with the description

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requirement. Rather, it is an attempt to preempt the future before it has arrived. (See *Fiers v. Revel*, 25 USPQ2d 1601 (CA FC 1993) and *Regents of the Univ. Calif. v. Eli Lilly & Co.*, 43 USPQ2d 1398 (CA FC, 1997)).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

#### ***Allowable Subject Matter***

Claims 82-95 and 98-115 are allowed.

Claim 97 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 703-305-4448.

The examiner can normally be reached on Monday through Friday 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 703-305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-9105 for regular communications and 703-746-9105 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

dms  
July 21, 2003



**JAMES KETTER  
PRIMARY EXAMINER**